

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:
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Date of mailing
(day/month/year) **26 APR 2005**

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

110/04075

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/IL04/00527

17 June 2004 (17.06.2004)

17 June 2003 (17.06.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61F 2/44 and US Cl.: 623/17.16

Applicant

DISC ORTHOPAEDIC TECHNOLOGIES INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL04/00527

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
 - ☐ paid additional fees under protest
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1,2,4-8 and 10-46

**WRITTEN OPINION OF THE
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International application No.
PCT/IL04/00527

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>16, 18-20, and 45</u>	YES
	Claims <u>1, 2, 4-8, 10-15, 17, 21-44, and 46</u>	NO
Inventive step (IS)	Claims <u>16, 19, and 45</u>	YES
	Claims <u>1, 2, 4-8, 10-15, 17, 18, 20-44, and 46</u>	NO
Industrial applicability (IA)	Claims <u>1, 2, 4-8, and 10-46</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1, 2, 4-8, 10-15, 17, 21-44, and 46 lack novelty under PCT Article 33(2) as being anticipated by PISHARODI (US 5,693,100). PISHARODI anticipates the claim language where the axial member as claimed is the screw (42) of PISHARODI; see Figures 6-9 and column 3, lines 40-58.

Regarding claim 10, the handle as claimed is the screwdriver of PISHARODI; see column 5, lines 6-9.

Regarding claim 11, the screw (42) can be unscrewed such that the claim language is considered inherently met.

Regarding claim 14, the channel as claimed is the screw thread of PISHARODI.

Regarding claim 23, the axis of rotation could be less than full axial rotation such that the claim language would be fully met if the rotation were slight or if along a radius of the device.

Regarding claim 39, there are inherently differences in the lengths of elements (32) and (34) such that the claim language is inherently met because manufacturing by machining or otherwise cannot result in exactly identical lengths for all similar elements.

Claims 18 and 20 lack an inventive step under PCT Article 33(3) as being obvious over PISHARODI (US 5,693,100) in view of KUSLICH (US 5,059,193). PISHARODI meets the claim language except for the bag around the tube as claimed. However, KUSLICH teaches that it was known to put a bag or covering over similar expandable tubes within the art; see Figures 19-21 and column 9, lines 10-52. Therefore, it is the Examiner's position that it would have been obvious to put a bag or covering over the PISHARODI device for the same reasons that KUSLICH did the same.

Claims 16, 19, and 45 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an axial member that extends from said tube and is adapted to function as a joint (claim 16), a biodegradable bag/covering over the tube (claim 19), or a self-expanding deformer (claim 45).

**WRITTEN OPINION OF THE
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International application No.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 4, 5, 28-31, 34, 35, 38, and 42 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 4, 5, 28-31, 34, 35, 38, and 42 are indefinite for the following reason(s):

Regarding claims 4 and 5, it is unclear what element of claim 1 is being modified.

Regarding claim 28, it is not understood where the axial force is coming from or being applied.

Regarding claims 29-31, the "pliable material" lacks antecedent basis.

Regarding claims 34 and 35, this claim language is not understood because the deformer must occupy 100% of the volume it takes up.

Regarding claim 38, it is not clear how axially displaced leaves can support each other based upon how the present device is disclosed.

Regarding claim 38, line 2, it is unclear why "configurations" is plural and how this language is intended to modify the base claim.

Regarding claim 42, the claim language is not understood based upon the fact that the leaves are in a tube and thus not in a flat or planar device. In other words, it is not clear now the leaves can be deformed from a plane since the tube surface is not planar.